THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

SHANNON MACK, and LINDSEY FARROW, *individually and on behalf of all others similarly situated*, Plaintiffs, v. AMAZON.COM, INC., Defendant.	CASE NO. C22-1310-JCC ORDER

This matter comes before the Court on Defendant's motion to dismiss Plaintiffs' first amended class action complaint ("FAC") (Dkt. No. 29). Having thoroughly considered the briefing and the relevant record, and finding oral argument unnecessary the Court DENIES the motion for the reasons explained herein.

I. BACKGROUND

Plaintiffs allege they purchased and used Solimo, a melatonin supplement manufactured and sold by Defendant on Amazon.com. (Dkt. No. 29 at 4, 6.) Solimo comes in two forms—tablet and gummy—with the label for each purporting to provide a specific dose of melatonin per serving (*e.g.*, 3mg or 5mg). (*Id.* at 4.) Melatonin is believed to manage the body's circadian rhythm (24-hour internal clock). (*Id.* at 1.) As such, it is commonly used as a sleep-aid. (*Id.*) Like any supplement, melatonin is regulated by the Food and Drug Administration ("FDA"), the

Federal Trade Commission ("FTC"), and state agencies. *See generally* FDCA, 21 U.S.C. § 301 *et seq*., 21 C.F.R. Part 100 *et seq.*, 21 U.S.C.S. § 343-1. The FAC asserts that Defendant, through its false labeling, substantially understates Solimo's true melatonin dosage in each serving. (Dkt. No. 26 at 5.) This, in turn, deceptively enticed Plaintiffs to purchase the product and has the capacity to do the same for others. (*Id.*)

According to Plaintiffs, the actual dosage of melatonin per serving, relative to the labeled amount, exceeds what would be a "reasonable excess" allowed by the FDA. (*Id.* at 7.) As Plaintiffs define it, a "reasonable excess" is any amount greater than that needed for a supplement to meet "the amount specified on the label throughout the product's shelf life." (*Id.* at 9 (quoting 21 C.F.R. § 101.36(f)(1)).) Plaintiffs assert that, as a result of this excess melatonin, they suffered injury. (*Id.* at 13–14.) Had they known Solimo's true melatonin dosage, they would not have purchased it *at any price*. (*Id.*)

Plaintiffs bring causes of action for (1) violations of Washington's Consumer Protection Act ("CPA"), (2) breach of contract, (3) breach of express warranty, and (4) breach of implied warranty. (*Id.* at 16–20.) Defendant moves to dismiss pursuant to Rules 12(b)(1) and 12(b)(6). (*See generally* Dkt. No. 29). It argues that (1) Plaintiffs lack standing; (2) the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts Plaintiffs' claims; (3) Plaintiffs fail to plausibly allege any of their causes of action; and, finally, that (4) Plaintiffs' breach of warranty claims are legally deficient. (*See* Dkt. No. 29 at 13–30.)

II. DISCUSSION

A. Legal Standards

Pursuant to Rule 12(b)(1), a complaint must be dismissed if the Court determines at any point that it lacks subject matter jurisdiction over the claims asserted. *Intl. Union of Operating Eng'rs. v. Cnty. of Plumas*, 559 F.3d 1041, 1043–44 (9th Cir. 2009). And if a plaintiff lacks standing, the Court lacks subject matter jurisdiction. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101–02 (1998). A Rule 12(b)(1) challenge may be facial or factual. Fed. R. Civ. P.

12(b)(1), *see Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). In a facial attack, such as this one, the defendant asserts a complaint's allegations are insufficient to confer federal jurisdiction. In reviewing such an attack, the Court assumes all material allegations in the complaint are true. *Thornhill Publ'g Co. v. General Tel. Elec.*, 594 F.2d 730, 733 (9th Cir. 1979). Whereas, upon a Rule 12(b)(6) motion, a complaint must be dismissed if it lacks a "cognizable legal theory" or "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted); *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). A claim is plausible when the "plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678.

B. Standing

In general, to establish standing, "a plaintiff must show (i) that [s]he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). This must be shown "for each claim that they press and for each form of relief that they seek." *Id.* at 2208. At the pleading stage, "general factual allegations of injury resulting from the defendant's conduct may suffice." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (internal citations omitted). This is not an onerous burden, though, "for on a motion to dismiss we presum[e] that general allegations embrace those specific facts that are necessary to support the claim." *Id.* Defendant contends that Plaintiffs lack standing to pursue (a) monetary relief because they have not alleged an injury-in-fact traceable to the products purchased and (b) injunctive relief because they have not alleged a certainly impending or substantial risk of future harm. (Dkt. No. 29 at 7.) Neither argument is persuasive.

As to the issue of an injury-in-fact, Plaintiffs allege that they "relied on the claimed melatonin content on Amazon's labels," that the bottles were "inaccurately labelled and

unreasonably overdosed," and had they known the true dosage, they "would not have purchased the product at the price [they] paid . . . [i]n fact, knowing the truth, [it] was worthless to [them]." (Dkt. No. 26 at 13, 15.) This is sufficient to allege a price injury. *See Reid v. Johnson & Johnson*, 780 F.3d 952, 958 (9th Cir. 2015) (price injury can be pleaded by alleging that one relies on a misrepresentation, had they known the truth, they would have paid less or, perhaps, nothing at all).[1] No more is required. Regarding future harm, Plaintiffs allege that, if not for the fact that they cannot confidently rely on Solimo's labeling, they would purchase the product again. (Dkt. No. 29 at 16.) Again, this is all that is required to establish injury. *See Davidson v. Kimberly-Clark Corporation*, 889 F.3d 956, 968–70 (2018) (injury can be actual and imminent if the plaintiff alleges that they would purchase the product again if they were able to confidently rely on the label).

Accordingly, the Court FINDS that Plaintiffs have sufficiently pleaded injury to support standing for the relief sought.

C. Preemption

To the extent a claim is preempted by federal law, it is legally deficient and subject to dismissal pursuant to Rule 12(b)(6). *See SmileCare Dental Group v. Delta Dental Plan of Calif., Inc.*, 88 F.3d 780, 783–84 (9th Cir. 1996). However, "FDA preemption, like all federal preemption, is an affirmative defense;" therefore, Defendant bears the burden. *Durnford v. MusclePharm Corp*., 907 F.3d 595, 603 n.8 (9th Cir. 2018). "Federal law imposes a comprehensive regulatory scheme for dietary supplements." *Lopez v. Zarbee's, Inc.,* 2023 WL 210878, slip op. at 1 (N.D. Cal. 2023). And "FDA regulations require that the quantity of

[1] Moreover, even if Plaintiffs received "the benefit of the bargain," as Defendant contends, (*see* Dkt. No. 29 at 15), they can still allege economic loss if they overpaid based on a misrepresentation. *See Guido v. L'Oréal*, 2011 WL 13152488, slip op. at 4–5 (C.D. Cal. 2011). Nor need Plaintiffs test the actual product purchased, *see Lorentzen v. Kroger Co.*, 532 F. Supp. 3d 901, 908 (C.D. Cal. 2021), as Defendant asserts. (*See* Dkt. No. 29 at 13–14.) An allegation that Defendant "is consistently selling the product purchased with false information" suffices. *Lorentzen*, 532 F. Supp. 3d at 908 (cleaned up).

melatonin 'be at least equal to the value . . . declared on the label' for the product's full shelf life." *Id.* (citing 21 C.F.R. § 101.9(g)(4)(i)). On this basis, Defendant asserts that Plaintiffs' claims are preempted because (1) the FDA permits melatonin overages and (2) Plaintiffs' allegations are supported by a test that deviates from the FDA's 12-sample testing protocol. (Dkt. No. 29 at 17–21.) Neither contention has merit.

1. Permissible Overages

Because supplements like melatonin degrade over time, the FDA allows manufactures to formulate the supplement with some overages to ensure "that the finished produced can meet the label declaration for that dietary ingredient through the product's shelf life." *Lopez,* 2023 WL 210878 at 1 (citing 68 Fed. Reg. 12158, 12203 (Mar. 13, 2002)). This "safe harbor" allows a reasonable excess over labeled amounts, so long as it is within "good manufacturing practice." 21 C.F.R. § 101.36(f)(1). But while the FDA allows for some overages, it does not intend to "allow the manufacturer to add excess dietary ingredients in unspecified amounts that would be in excess of the amount actually needed to meet the label declaration." *Lopez,* 2023 WL 210878 at 1 (citing 68 Fed. Reg. 12158, 12203 (Mar. 13, 2002)). Said another way, if a product's label falsely states the dosage, relative to this permissible excess, the product is mislabeled. *See Durnford,* 907 F.3d 595 at 601.

Relying on the fact that the FDA allows some overages, Defendant contends that Plaintiffs' claims are preempted. (Dkt. No. 29 at 11–12.) Specifically, Defendant asserts that, by alleging they wanted "a 5mg dose and no more," Plaintiffs ostensibly contend that *any* amount of melatonin over this amount is "unreasonable, misleading, and deceptive." (*Id.* at 12.) And based on the FDA's requirement that a supplement contain a minimum dose at the end of its shelf life, thereby requiring additional melatonin at the beginning, Plaintiffs' claims are preempted. (*Id.* at 10–11.) This misconstrues Plaintiffs' allegations.[2] They state that "by selling inaccurately

[2] Also, the Court notes that Defendant's cited cases here are not helpful. They involve false advertising claims based on structure/function and "unreasonable consumer" claims—not

labeled and *unreasonably* overdosed Solimo Melatonin, Amazon engaged in unfair and deceptive practice." (Dkt. No. 26 at 18 (emphasis added).) Plaintiffs recognize that *some* overage is allowed, but contend that the amount in Solimo "increases the risk of adverse side effects" and puts at issue its "long-term safety" and, for these reasons, it is an "unreasonable excess . . . prohibited (not permitted) by FDA regulations" and results in "false and misleading labeling." (*Id.* at 12.)

Defendant next contends Plaintiffs are trying to impose a "made-up standard, under which any overage greater than 10–15% of the labeled amount is *per se* unreasonable." (Dkt. No. 29 at 19.) Again, this mischaracterizes the FAC. It articulates such a range to compare Solimo's melatonin overage to others. (Dkt. No. 26 at 10). The only limit that Plaintiffs ask be enforced is that set by the FDA, (*see* Dkt. No. 26 at 9), *i.e.*, the "amount actually needed to meet the label declaration." *Ochoa v. Church & Dwight Co., Inc.*, 2018 WL 4998293, slip op. at 4 (C.D. Cal. 2018).

2. Testing

The FDA requires that compliance with food labeling requirements be determined through a 12-sample testing protocol. *See* 21 C.F.R. § 101.9(g)(2). Defendant argues that, because the FAC does not allege that Plaintiffs actually used this protocol when testing Solimo, their claims are preempted. (Dkt. No. 29 at 21.)

But *Durnford* clarified the scope of the testing requirement, at least for pleading purposes. *See* 907 F.3d at 603 n.8. It indicated that "plaintiffs are generally not expected to provide evidence in support of their claims at the pleading stage . . . nor are they required to plead the 'probability' of their entitlement to relief." *Id.* While this was not central to the *Durnford* holding, many courts have since adopted its reasoning, holding that a plaintiff need not comply with the FDA's 12-sample protocol at the pleading stage. *See e.g., Murphy v. Olly Public*

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ingredient overages. (*See, e.g.*, Dkt. No. 29 at 17–19 (citing *Greenberg v. Target Corp.*, 985 F.3d 650 (9th Cir. 2021); *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 848 (9th Cir. 2019)).)

Benefit Corporation, 2023 WL 210838, slip op. at 6 (N.D. Cal. 2023). While Defendant contends otherwise, the cases it cites in support are primarily pre-*Durnford* and, regardless, in the minority. (*See* Dkt. No. 29 at 21.) The Court sees no reason to depart from the majority of cases. Applying this standard, Plaintiffs' allegations are sufficient to avoid preemption on the issue of testing, at least at the pleading stage.[3] Nor has Defendant shown that Plaintiffs have "pleaded themselves out of court by pleading facts that establish [Defendant's] compliance with FDA regulations." *Murphy*, 2023 WL 210838, at 7.

As such, the Court FINDS that Plaintiffs claims are not preempted.

D. Plausibility of Claims

Defendant next makes a series of plausibility arguments supporting Rule 12(b)(6) dismissal. The first, though, is a regurgitation of its standing argument. (*See* Dkt. No. 29 at 22 (contending that the FAC fails to plausibly state the injury required for any of Plaintiffs' claims).) The Court rejects it for the same reasons it did above. *See supra* Part II.B. The remaining two, (*see* Dkt. No. 29 at 22–27), while also without merit, require some discussion.

As federal courts frequently repeat, a cause of action must be supported by more than labels and conclusions. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). While "Rule 8 does not require detailed factual allegations, it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678 (cleaned up). It requires plausible allegations supporting each cause of action. *See id.* And to the extent a claim sounds in fraud or mistake, the complaint "must state with particularity the circumstances." Fed. R. Civ. P. 9(b). This is often referred to as the "who, what, when, where, and how" enhanced pleading standard.

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[3] According to the FAC, Plaintiffs tested bottles of Solimo comparable to what they consumed, which resulted in the discovery of significant melatonin excesses over the amount(s) indicated on each label. (*See* Dkt. No. 26 at 8–9.) The FAC further alleges that third-party testing confirms such overages are common and widespread in the industry. (*Id.*) In addition, they contend that Defendant possesses unique knowledge to confirm these excesses throughout Defendant's Solimo product line. (*Id.*) This is because Defendant has testing data unavailable to Plaintiffs, at least without discovery (*Id.*)

Cafasso, United States ex rel. v. Gen. Dynamics C4 Sys., Inc., 637 F.3d 1047, 1055 (9th Cir. 2011).

According to Defendant, the "logical leap" here between the FAC's allegations and that required by Rule 9 is simply too great. (Dkt. No. 32 at 15.) The Court disagrees. The FAC's allegations are sufficiently particular to support a CPA claim, irrespective of whether Rule 9 applies. (*See* Dkt. No. 26 at 8–9, 15–16.) This is particularly true in light of the FAC's contention that Defendant possesses non-public FDA compliance testing data regarding the actual melatonin dosage within Solimo sold. (*See id.* at 26 at 9.) As such, it would be unfair to dismiss the FAC before Plaintiffs have the opportunity to see this data. *See Nayab v. Capital One Bank (USA), N.A.*, 942 F.3d 480, 495 (9th Cir. 2019).

Defendant also asserts that, because the FAC does not affirmatively identify *which* contract Defendant breached and *when* the breach occurred, it fails to plausibly allege a breach of contract claim. (Dkt. No. 29 at 27.) But this relies on an obtuse interpretation of the FAC. It is black letter law that the Court must accept Plaintiffs' allegations as true and draw reasonable inferences in their favor. *See Vasquez v. Los Angeles Cnty.*, 487 F.3d 1246, 1249 (9th Cir. 2007). Defendant would ask the Court to do otherwise.

According to the FAC, when Defendant advertises Solimo as for sale on its website, the listing contains a copy of the nutritional label. (*See* Dkt. No. 26 at 6–7, 14–16.) And it is reasonable to infer that consumers can glean other key terms from this listing, such as the product's price and quantity. When Defendant shipped the product to Plaintiffs, Defendant was bound by those terms. (*See id.* at 19–20.) This is all that is required to establish a contract, *see, e.g.*, *Becker v. Washington State U.*, 266 P.3d 893, 899 (Wash. App. 2011), even in the internet age, *see, e.g.*, *Nguyen v. Barnes & Noble, Inc.*, 2015 WL 12766130, slip op. at 6 (C.D. Cal. June 16, 2015).

Accordingly, the Court FINDS that the FAC plausibly alleges all claims against Defendant, including breach of contract.

E. Breach of Warranty Claims

Finally, Defendant moves to dismiss the FAC's breach of express and implied warranty claims, arguing they are legally deficient in light of (a) the disclaimer contained in Defendant's standard Conditions of Use ("COU") and (b) Plaintiffs' failure to adequately plead notice. (Dkt. No. 29 at 27–30.) In support, Defendant introduces facts and evidence outside of the FAC, namely the COU. (*See* Dkt. No. 30-1 at 29–34.) This is not appropriate in a Rule 12(b)(6) motion.[4] *See Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). And the Court DECLINES to consider this issue.

III. CONCLUSION

For the foregoing reasons, the Court DENIES Defendant's motion to dismiss.

DATED this 16th day of March 2023.

John C. Coughenour
UNITED STATES DISTRICT JUDGE

[4] Perhaps the Court could take judicial notice of the COU and its terms. *See* Fed. R. Evid. 201(b). But Defendant makes no affirmative request or argument supporting such a request. (*See generally* Dkt. Nos. 29, 32.) Therefore, the Court will not consider the import of the COU and its terms in deciding Defendant's Rule 12(b)(6) motion. *See Indep. Towers of Washington v. Washingto*n, 350 F.3d 925, 929 (9th Cir. 2003) ("Judges are not like pigs, hunting for truffles buried in briefs.").